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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,555	03/14/2001	Akira Takashima	A33865/090495.0233	3921

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NEW YORK, NY 10112

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/808,555	<b>Applicant(s)</b> TAKASHIMA ET AL.	
	<b>Examiner</b> G. R. Ewoldt, Ph.D.	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 8/28/03, 11/10/03, and 1/07/04.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-48,65-69,121 and 133 is/are pending in the application.
- 4a) Of the above claim(s) 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-48,65,66,69,121 and 133 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 44-48, 65-66, 69, 121, and 133 are being acted upon.
2. Applicant's amendments and remarks, filed 8/28/03 and 1/07/04, and IDS, filed 11/10/03, are acknowledged. In view of Applicant's amendment, all previous rejections have been withdrawn. Accordingly, Applicant's remarks have been rendered moot.
3. The following are new grounds for rejection necessitated by Applicant's amendment.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:  
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 44-48, 65, 66, 69, 121, and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,817,343 (1998) in view of Kim et al. (1998, IDS) and Kellermann et al. (1999, IDS).

The '343 patent teaches a method for providing an artificial chemotactic factor gradient *in vivo* comprising administering an ethylene-vinyl-acetate (see particularly column 7, line 9) device (see particularly column 1, line 18), subcutaneously (see particularly column 11, line 41), said device comprising a chemotactic factor, said factor comprising a chemokine (see particularly column 4, line 63), and that said administration is useful for the controlled or sustained release of drugs (see particularly column 1, lines 5-15).

The reference teaching differs from the claimed invention only in that it does not teach the use of the chemokine MIP-3 $\beta$  and the entrapment of antigen presenting cells.

Kim et al. teaches that MIP-3 $\beta$  is a strong chemoattractant for T cells and mature B cells (see particularly page 2418, column 2, paragraph 2).

Kellermann et al. teaches that MIP-3 $\beta$  is a strong chemoattractant for dendritic cells (DCs) and that the colocalization of T cells and DCs is required for efficient initiation of T cell-dependent immunity (see particularly page 3859, column 1, paragraph 1 and page 3861, column 1, paragraph 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide an artificial chemotactic factor gradient *in vivo* comprising administering an ethylene-vinyl-acetate device subcutaneously, said device comprising a chemotactic factor, said factor comprising a chemokine, as taught by the '343 patent, employing the specific chemokine MIP-3 $\beta$ , as taught by Kim et al. One of ordinary skill in the art at the time the invention was made would have been motivated to use the specific chemokine MIP-3 $\beta$  in the device of the '343 patent because said chemokine is a strong chemoattractant for both T cells, as taught by Kim et al., and DCs, as taught by Kellermann et al. and would thus prove useful in a controlled or sustained release device for the efficient initiation of T cell-dependent immunity, as taught by Kellermann et al. because said device would cause the colocalization of both T cells and DCs.

6. No claim is allowed.

7. Applicant's amendment or action (filing of new applications) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to

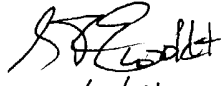
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5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

9. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600

  
3/30/04  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**